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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,804	08/03/2006	Mallen Huang	1503-1083	6727

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
05/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,804	HUANG, MALLEN	
	Examiner	Art Unit	
	SHANON A. FOLEY	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-83 and 86-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *84 and 85* is/are allowed.

6)☒ Claim(s) *75-83 and 86-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 75 is objected to because of the following informalities: an article is missing between "express" and "P2". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 75-79, 81, 82 and 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kontani et al. (Cancer Gene Therapy. 2002; 9: 330-337), Kikuchi et al. (Blood. 2000; 96 (1): 91-99) and Krug et al. (European Journal of Immunology. 2001; 31: 3026-3037).

Kontani et al. teach a nucleotide vaccine composition comprising a mixture (top of first column on page 332) of a plasmid encoding an antigen, MUC1 (see "plasmid DNA" on page 331) and a subclass of antigen-presenting dendritic cells (see Preparation of DCs on page 331) and the top of page 332 describing the "combination of DNA and DC's". The nucleotide sequence of Kontani et al. is produced by cloning nucleotide sequence encoding an MHC-binding protein into a vector and propagated in a tumor cell line, see "Plasmid DNA" and Transfection of MUC1 cDNA..." on page 331. The antigen-presenting cells of Kontani et al. are generated by isolating antigen-presenting cells from a subject, see "Preparation of DCs" on page 331. Although Kontani et al. do not pre-incubate the plasmid and the dendritic cells together,

Kontani et al. certainly suggest the benefits of doing so since antitumor immunity was enhanced upon simultaneous administration at the same site, see the last two paragraphs of the discussion section bridging pages 335-336. Kontani et al. teach producing an immune response by administering the vaccine composition, see the paragraph bridging pages 331-332.

Kontani et al. do not teach or suggest modifying a plasmacytoid dendritic cell to express CD40L or adding an unmethylated CpG sequence to a nucleic acid sequence encoding the tumor antigen of Kontani et al.

Kikuchi et al. teach modifying dendritic cells to express CD40L, see "cytokines" on page 92.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify dendritic cells to express CD40L to enhance T-cell activation and anti-tumor antigen presentation, see Figure 8 on page 96, the paragraph bridging the columns on page 97 and "Dendritic cell-based cancer immunotherapy" bridging pages 97-98.

Neither Kikuchi et al. nor Kontani et al. teach or suggest modifying a plasmacytoid-type dendritic cell or adding an unmethylated CpG sequence to a nucleic acid sequence encoding the tumor antigen.

However, Krug et al. teach toll-like receptors on plasmacytoid dendritic cells are required for recognition of CpG motifs, see Krug et al. also specifically demonstrate that synergistic activation of plasmacytoid dendritic cells, stimulating the production of IL-12, IFN-α and bioactive IL-12 p70, see section 2.4 and Figures 5 and 9.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the plasmacytoid dendritic cells of Krug et al. to express CD40L and to add

the CpG motif to the nucleotide antigen vaccine of Kontani et al. to induce a synergistic activation of PDCs for production of IL-12. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for inducing synergistic activation of PDCs in the presence of CD40L and a CpG nucleotide motif since Krug et al. specifically teach that toll-like receptors present on PDCs are responsible for recognition of CpG motifs and that synergistic activation of PDC's is accomplished through simultaneous presence of CD40L and CpG nucleic acids. One of ordinary skill in the art at the time the invention was made would have had further reasonable expectation of success for modifying PDC's to express CD40L since Kikuchi et al. demonstrate successful expression of CD40L on dendritic cells.

Applicant states that Kontani et al. differs from the instant invention since the two constituents of Kontani et al. are administered as separate injections.

Applicant's arguments have been fully considered, but are found unpersuasive. Kontani et al. explicitly teach that the DNA and dendritic cells were administered simultaneously at the same site, see the paragraph above the "Materials and Methods" section on page 331 and the very top of page 332. Therefore, even though the two components of Kontani et al. are administered separately, they are administered at the same time and at the same site, which at least suggests a vaccine mixture in situ.

Applicant also points out the limitations not taught by Kontani et al., now recited in newly presented independent claims.

However, the limitations not taught by Kontani et al. are taught by other references used in combination with the teachings of Kontani et al.

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kontani et al., Kikuchi et al. and Krug et al. as applied to claims 75-79, 81, 82 and 86-90 above, and further in view of Ni et al. (Journal of Biological Chemistry. 2002; 277 (15): 12689-12696).

See the teachings of Kontani et al., Kikuchi et al. and Krug et al. above. None of the references teach or suggest antigen-presenting cells expressing a P2 receptor.

However, Ni et al. teach dendritic cells nucleotide receptors from the P2X family, see Figure 5.

One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate a PX2 receptor in a dendritic cell with a reasonable expectation of success in the vaccine composition of Kontani et al., Kukichi et al. and Krug et al. to enhance DC activation, see page 12693 of Ni et al.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kontani et al., Kikuchi et al. and Krug et al. as applied to claims 75-79, 81, 82 and 86-90 above, and further in view of Fritz et al. (WO 02/069900).

See the teachings of Kontani et al., Kikuchi et al. and Krug et al. above. None of the references teach or suggest SEQ ID NO: 5.

However, Fritz et al. teach a sequence comprising instant SEQ ID NO: 5, see the sequence alignment provided below:

```
Query Match          100.0%; Score 47; DB 1; Length 21;
Best Local Similarity  100.0%;
Matches   9; Conservative   0; Mismatches   0; Indels   0; Gaps   0;

Qy       1 AFHGDAEAL 9
           |||||||||
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Db 5 AFHGDAEAL 13

One of ordinary skill in the art at the time the invention was made would have been motivated to use the fusion protein sequence of Fritz et al. with a reasonable expectation of success in the vaccine composition of Kontani et al., Kukichi et al. and Krug et al. to treat cancer, see claim 29 of Fritz et al.

Allowable Subject Matter

Claims 84 and 85 are allowed. The prior art does not teach or suggest SEQ ID NOs 3 or 4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on (571) 272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHANON A. FOLEY/
Primary Examiner
Art Unit 1648